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AWARD NUMBER: W81XWH-09-1-0120

TITLE: Pilot study of Gleevec/Imatinib Mesylate (STI-571, NSC 716051) In Neurofibromatosis (NF1) Patients with Plexiform Neurofibromas

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The protocol was submitted to the Indiana University Cancer Center Scientific Review board on July 31, 2009. The Scientific Review board approved the protocol on Oct 7, 2009. The protocol was also submitted to the Indiana University Institutional Review Board on July 31, 2009 and we received final approval 10/29/2009. These documents were submitted to the DOD on 11/2009. We received the DOD provisions on 1/19/2010 and returned the response to the provisions on 2/18/2010. The protocol was amended to include the provisions from the DOD and Novartis and submitted to our IRB 3/16/2010. We received IRB approval of Amendment #1 on 3/29/2010. We received final DOD approval 6/4/2010 . We enrolled our first subject on 6/30/2010. We have enrolled 19 patients to date. We amended the study to include pediatric patients. We have requested and received a no-cost extension to complete enrollment of the pediatric cohort. The last patient is scheduled to be enrolled on 9/27/2013

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Section I - Introduction of research

The goal of this Pilot Study is to trial multiple techniques for determining the response of NF1 patients with plexiform neurofibromas to Gleevec® therapy for use in subsequent clinical trials. The impact of this proposal is having a better way to measure/quantify the response of plexiform neurofibromas in NF1 patients to treatment.

Section II – Body (Progress to date)

The protocol was submitted to the Indiana University Cancer Center Scientific Review board on July 31, 2009. The Scientific Review board approved the protocol on Oct 7, 2009. The protocol was also submitted to the Indiana University Institutional Review Board on July 31, 2009 and we received final approval 10/29/2009. These documents were submitted to the DOD on 11/2009. We received the DOD provisions on 1/19/2010 and returned the response to the provisions on 2/18/2010. The protocol was amended to include the provisions from the DOD and Novartis and submitted to our IRB 3/16/2010. We received IRB approval of Amendment #1 on 3/29/2010. At this time we are waiting on HRPO approval from Dr. Widemann at the NCI who is a coinvestigator on this trial. This is the final item requested by DOD. We received final DOD approval 6/4/2010 . We enrolled our first subject on 6/30/2010. We have enrolled 19 patients to date. We amended the study to include pediatric patients. We have requested and received a no-cost extension to complete enrollment of the pediatric cohort. The last patient is scheduled to enroll on 9/27/2013

Section III – Key Research Accomplishments/Reportable outcomes

No data available at this time.

Section IV – Conclusions

No data available at this time. Data continues to be collected and will be analyzed upon completion of accrual and completion of treatment for the 6 month time point.

Report is to be submitted via email to the following addresses:

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(Subject line of email USAMRAAGrant/Cooperative award # W81xwh-09-1-0120)